

Appl. Serial No. 10/688,489  
Amendment dated April 21, 2006  
Reply to Office Action of January 27, 2006

### **REMARKS**

Applicant acknowledges receipt of the Communication mailed January 27, 2006. There are no prior art rejections against the claims.

Applicant thanks Examiner Lucas for extending to Applicant's Representative the courtesy of a telephone interview that took place April 18, 2006. During the interview Applicant's Representative clarified that the "other promoter-primers" referenced in the Specification in the paragraph spanning pages 58-59 as performing poorly at the indicated target input levels were the ones particularly identified in that paragraph. The distinction between the working and non-working primers defined a boundary between primer sequence domains. The instant claims embrace primers that gave superior results, and do not embrace primers that performed poorly under the indicated conditions. Based on the interview, Applicant is of the understanding that instant Claim 18 represents allowable subject matter.

Claims 18, 23 and 29 are amended herein, and Claims 20-22 have been canceled.

Claims 18-19, 23-26 and 29-30 will be pending after entry of the present Amendment.

No new matter is added by the present Amendment.

Entry of this Response is respectfully requested.

### **The Enablement Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 18-25 and 29-30 have been rejected under the enablement requirement of § 112, first paragraph. Applicant notes that the rejection of Claims 20-22 is no longer relevant in view of the cancellation of those claims. The Examiner has noted that the application teaches that the

Appl. Serial No. 10/688,489  
Amendment dated April 21, 2006  
Reply to Office Action of January 27, 2006

operability of a primer consisting of a fragment of SEQ ID NO:74 in combination with a primer consisting of a fragment of SEQ ID NO:59 represents an unexpected result in view of the failure of certain other primer combinations. The claims have been rejected because they embrace sequences shown to perform poorly.

The amended claims comply with the enablement requirement of § 112. More specifically, Claim 18 has been amended to require that the 3'-end of the recited first primer fall within the sequence of SEQ ID NO:74, and that the 3'-end of the recited second primer fall within the sequence of SEQ ID NO:59. Support for the amendment can be found in the second paragraph on page 31, particularly at lines 20-22 and at lines 26-29. These sections of the Specification describe that preferred primers "have target-complementary sequences contained within" one of the recited sequence domains (*i.e.*, SEQ ID NO:59 or SEQ ID NO:74). The desirability of the claimed "first" primers is reiterated on page 59 at lines 1-3. The dependencies of Claims 23 and 29 have been amended to conform with the cancellation of Claims 20-22.

It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. (*In re Vaeck* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)) Moreover, enablement is not precluded by the necessity for some experimentation such as routine screening. (*In re Wands*, 858 F.2d, 8 USPQ2d at 1404; MPEP § 2164.01) In the instant case, the Specification sets forth the sequences of SEQ ID NO:59 and SEQ ID NO:74, from which useful "first" and "second" primers were derived, sets forth length parameters and minimum numbers of necessary contiguous bases from these sequences, sets forth screening methods and criteria for identifying useful primers, and sets forth exemplary primers established by these methods. Identifying additional primers having 3' terminal target-complementary sequences contained within SEQ ID NO:59 (a 31-mer) or SEQ ID NO:74 (a 24-mer) represents no more than routine experimentation in the art field related to the design of nucleic acid amplification assays.

Appl. Serial No. 10/688,489  
Amendment dated April 21, 2006  
Reply to Office Action of January 27, 2006

The instant Specification enables the claimed combination of primers from domains within the West Nile virus genome which are disclosed to be particularly useful for conducting highly sensitive assays. Since Claim 18 has been amended to recite first and second primers having 3' terminal target-complementary sequences contained respectively within SEQ ID NO:74 and SEQ ID NO:59, since the Specification discloses the use of representative primers derived from SEQ ID NO:74 in combination with representative primers derived from SEQ ID NO:59, Applicant submits that the pending claims are enabled in their full scope. Accordingly, withdrawal of the enablement rejection is appropriate.

**The Written Description Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 18-25, 29 and 30 have been rejected as failing to comply with the written description requirement under § 112, first paragraph. Applicant notes that the rejection of Claims 20-22 is no longer relevant in view of the cancellation of those claims. The rejection expresses that the claims exceed the genus for which adequate description was provided by permitting the inclusion of target-complementary sequences other than those specifically shown to work.

The amended claims comply with the written description requirement of § 112. As indicated above, the amended claims require that the 3'-end of the recited first primer fall within the sequence of SEQ ID NO:74, and that the 3'-end of the recited second primer fall within the sequence of SEQ ID NO:59. Descriptive support for the amendment is cited herein under the preceding section. Applicant notes that the written description requirement of 35 U.S.C. § 112, first paragraph, does not require a description of the complete structure of every species within a chemical genus. See *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) ("A specification may, within the meaning of 35 U.S.C. § 112, first paragraph, contain a written description of a broadly claimed invention without describing all species the claim encompasses.")

Appl. Serial No. 10/688,489  
Amendment dated April 21, 2006  
Reply to Office Action of January 27, 2006

Since the language of amended Claim 18 defines a genus of first primers and a genus of second primers using formulae reciting contiguous sequences of bases contained within particularly identified larger sequences, and analogous to the chemical arts wherein a formula is normally an adequate description of a claimed genus, the pending claims are presented as complying with the written description requirement of § 112. Accordingly, withdrawal of the written description rejection is requested.

#### CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the telephone number shown below.

#### DEPOSIT ACCOUNT INFORMATION

No fees are believed due in this filing. However, if Applicant is mistaken, please charge any fees due in connection with this Reply to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

#### CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to (571) 273-8300 on the date indicated below to Mail Stop Amendment,

Appl. Serial No. 10/688,489  
Amendment dated April 21, 2006  
Reply to Office Action of January 27, 2006

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Respectfully submitted,  
GEN-PROBE INCORPORATED

Dated: April 21, 2006

By: 

Michael J. Gilly  
Registration No. 42,579  
Gen-Probe Incorporated  
10210 Genetic Center Drive  
San Diego, CA 92121  
(858) 410-8657

GP140-04.UT.ROA2.wpd